

CLAIMS

1. Film-shaped medicament for buccal administration of galanthamine or a salt or derivative thereof, said medicament comprising at least one layer which contains a cholinergic active substance acting on the central nervous system, or a combination of at least two such active substances, and said active substance(s) being selected from the group comprising galanthamine, pharmaceutically acceptable salts of galanthamine, galanthamine derivatives and their pharmaceutically acceptable salts.
2. Film-shaped medicament according to claim 1, characterized in that the said layer or at least one of the layers has a polymer matrix serving as active substance reservoir, the polymer content amounting to 5 to 95%, preferably 15 to 75%-wt, with particular preference 20 to 50%-wt.
3. Film-shaped medicament according to claim 1 or 2, characterized in that it is soluble in aqueous media or/and rapidly disintegrates in aqueous media but is not mucoadhesive.
4. Film-shaped medicament according to any one of the preceding claims, characterized in that it is mucoadhesive, but is insoluble or only partially soluble or disintegratable in aqueous media.
5. Film-shaped medicament according to any one of the preceding claims, characterized in that it is mucoadhesive and
- soluble or disintegratable in aqueous media, or

- capable of gelling or swelling in aqueous media.

6. Film-shaped medicament according to any one of the preceding claims, characterized in that within 30 min, preferably within 15 min, with particular preference within 5 min after application it releases such an amount of the active substance(s) contained therein to the oral cavity that an effective plasma level is achieved.

7. Film-shaped medicament according to any one of the preceding claims, characterized in that it is of a bilayer or multilayer structure, with at least one layer containing active substance.

8. Film-shaped medicament according to any one of the preceding claims, characterized in that at least one of the layers has a retarded active substance release.

9. Film-shaped medicament according to any one of the preceding claims, characterized in that the active substance content is 0.1 to 30%-wt, preferably 1 to 20%-wt., each relative to the active substance-containing layer(s).

10. Film-shaped medicament according to any one of the preceding claims, characterized in that the medicament contains galanthamine, or a salt or derivative of galanthamine, in combination with at least one further pharmaceutically active substance, preferably selected from the group of the acetylcholinesterase inhibitors.

11. Film-shaped medicament according to any one of the preceding claims, characterized in that its layer thickness is 0.01 to 5 mm, preferably 0.03 to 2 mm, with particular preference 0.05 to 1 mm.

12. Film-shaped medicament according to any one of the preceding claims, characterized in that it contains one or more auxiliaries selected from the group comprising fillers, colourants, emulsifiers, plasticizers, disintegration promoters, disintegrants (wick agents), wetting agents, sweetening and flavouring agents, preservatives, pH regulators, permeation-enhancing substances and antioxidants.

13. Use of at least one cholinergic active agent acting on the central nervous system, selected from the group comprising galanthamine, pharmaceutically acceptable salts of galanthamine, galanthamine derivatives and their pharmaceutically acceptable salts, for the production of a film-shaped buccal medicament intended for transmucosal administration of the said active substance(s) for treating diseases or disease symptoms accompanied by, or caused by, a lack of acetylcholine-induced conduction and/or a disturbed regulation of neuronal nicotinic receptors.

14. Use according to claim 13, characterized in that the said film-shaped medicament is a medicament according to claims 1 to 12.

15. Use according to claim 13 or 14, characterized in that the said disease is Alzheimer's disease or that the said symptom is impaired memory occurring in the course of Alzheimer's disease.

16. Use according to claim 13 or 14, characterized in that the said treatment is the therapy of alcohol abuse, especially a treatment for reducing the craving for alcohol, or the therapy of nicotine abuse, especially a treatment for reducing the craving for nicotine.

17. Use according to claim 13 or 14, characterized in that the said treatment is an antidote treatment following neuroleptic anaesthesia.

18. Use according to claim 13 or 14, characterized in that the said treatment is a therapy of abuse of chemical substances or of the dependence on such substances, especially a therapy of intoxication with psychotropic substances.

19. Use according to claim 13 or 14, characterized in that the said symptoms or diseases are symptoms of jet lag or other disorders of the physiological rhythm of body functions.

20. Use according to claim 13 or 14, characterized in that the said symptoms or diseases are chronic fatigue syndrome or disturbed sleep.

21. Use according to claim 13 or 14, characterized in that the said disease is schizophrenia or a mania.

22. Use according to claim 13 or 14, characterized in that the said diseases or symptoms are neurological illnesses and symptoms, especially paralytic symptoms.

23. Use according to claim 13 or 14, characterized in that the medicament is used for the treatment of disorders of the central nervous system occurring as a consequence of the action of psychotropic substances caused by occasional or chronic use or abuse of addictive substances, narcotics or medicaments, or as a side effect of the use of medicaments as intended, especially repeated or prolonged use of medicaments, or as a consequence of acute

poisoning, or as a consequence of the chronic action of poisons, in humans or other vertebrates.

24. Use according to claim 23, characterized in that the said symptoms are symptoms from the group comprising cognitive disorders, especially impaired memory, as well as impairment of memory performance, impaired perception, impaired coordination of movements.

25. Method for treating a person suffering from one of the diseases mentioned in claims 13 to 24 or from one of the symptoms mentioned in claims 13 to 24, or who is affected by a dependence on one or more chemical substances, in which method the person to be treated is buccally administered a therapeutically effective dose of at least one cholinergic active substance acting on the central nervous system from the group comprising galanthamine, pharmaceutically acceptable salts of galanthamine, galanthamine derivatives and their pharmaceutically acceptable salts, in the form of a film-shaped medicament.

26. Method according to claim 25, characterized in that the film-shaped medicament is used according to any one of claims 1 to 12.

- AMENDED SHEET

6. Film-shaped medicament according to any one of the preceding claims, characterized in that the active substance content is 0.1 to 30%-wt, preferably 1 to 20%-wt., each relative to the active substance-containing layer(s).
7. Film-shaped medicament according to any one of the preceding claims, characterized in that the medicament contains galanthamine, or a salt or derivative of galanthamine, in combination with at least one further pharmaceutically active substance, preferably selected from the group of the acetylcholinesterase inhibitors.
8. Film-shaped medicament according to any one of the preceding claims, characterized in that its layer thickness is 0.01 to 5 mm, preferably 0.03 to 2 mm, with particular preference 0.05 to 1 mm.
9. Film-shaped medicament according to any one of the preceding claims, characterized in that it contains one or more auxiliaries selected from the group comprising fillers, colourants, emulsifiers, plasticizers, disintegration promoters, disintegrants (wick agents), wetting agents, sweetening and flavouring agents, preservatives, pH regulators, permeation-enhancing substances and antioxidants.
10. Use of at least one cholinergic active agent acting on the central nervous system, selected from the group comprising galanthamine, pharmaceutically acceptable salts of galanthamine, galanthamine derivatives and their pharmaceutically acceptable salts, for the production of a film-shaped buccal medicament intended for transmucosal administration of the said active substance(s) for treating diseases or disease symptoms accompanied by, or caused by, a lack of acetylcholine-induced conduction and/or a disturbed regulation of neuronal nicotinic receptors.

11. Use according to claim 10, characterized in that the said film-shaped medicament is a medicament according to claims 1 to 9.
12. Use according to claim 10 or 11, characterized in that the said disease is Alzheimer's disease or that the said symptom is impaired memory occurring in the course of Alzheimer's disease.
13. Use according to claim 10 or 11, characterized in that the said treatment is the therapy of alcohol abuse, especially a treatment for reducing the craving for alcohol, or the therapy of nicotine abuse, especially a treatment for reducing the craving for nicotine.
14. Use according to claim 10 or 11, characterized in that the said treatment is an antidote treatment following neuroleptic anaesthesia.
15. Use according to claim 10 or 11, characterized in that the said treatment is a therapy of abuse of chemical substances or of the dependence on such substances, especially a therapy of intoxication with psychotropic substances.
16. Use according to claim 10 or 11, characterized in that the said symptoms or diseases are symptoms of jet lag or other disorders of the physiological rhythm of body functions.
17. Use according to claim 10 or 11, characterized in that the said symptoms or diseases are chronic fatigue syndrome or disturbed sleep.

18. Use according to claim 10 or 11, characterized in that the said disease is schizophrenia or a mania.

19. Use according to claim 10 or 11, characterized in that the said diseases or symptoms are neurological illnesses and symptoms, especially paralytic symptoms.

20. Use according to claim 10 or 11, characterized in that the medicament is used for the treatment of disorders of the central nervous system occurring as a consequence of the action of psychotropic substances caused by occasional or chronic use or abuse of addictive substances, narcotics or medicaments, or as a side effect of the use of medicaments as intended, especially repeated or prolonged use of medicaments, or as a consequence of acute poisoning, or as a consequence of the chronic action of poisons, in humans or other vertebrates.

21. Use according to claim 20, characterized in that the said symptoms are symptoms from the group comprising cognitive disorders, especially impaired memory, as well as impairment of memory performance, impaired perception, impaired coordination of movements.

22. Method for treating a person suffering from one of the diseases mentioned in claims 10 to 21 or from one of the symptoms mentioned in claims 10 to 21, or who is affected by a dependence on one or more chemical substances, in which method the person to be treated is buccally administered a therapeutically effective dose of at least one cholinergic active substance acting on the central nervous system from the group comprising galanthamine, pharmaceutically acceptable salts of galanthamine, galanthamine derivatives and their pharmaceutically acceptable salts, in the form of a film-shaped medicament.

23. Method according to claim 22, characterized in that the film-shaped medicament is used according to any one of claims 1 to 9.